

Implant Summary Report for:

Heraeus Medical

Hips using Palacos Antibiotic Cement

Comprising PRIMARY hips implanted up to:	13 January 2024
NJR Database extract:	12 February 2024
Produced on:	23 February 2024
Licensed for use until:	23 February 2025

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This report has been produced by the National Joint Registry (NJR). It summarises usage and outcomes associated with the Hips using Palacos Antibiotic Cement up to the specified dates. This analysis is based on data collected by the NJR and PROMs data collected by NHS Digital for the following combinations of products:

Cemented Components Hips using Palacos Antibiotic Cement

Appendix A lists details of all Palacos Antibiotic Cement products included in this report.

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NJR Recorded Usage

Implant Usage

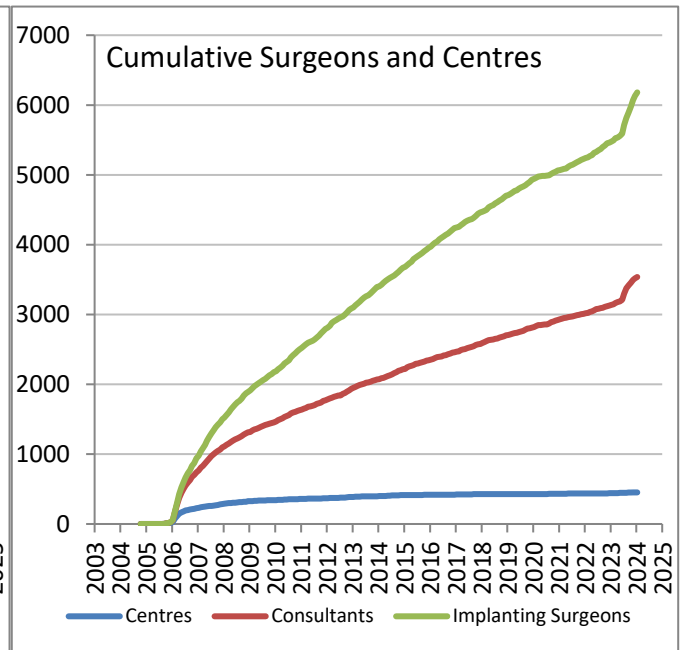
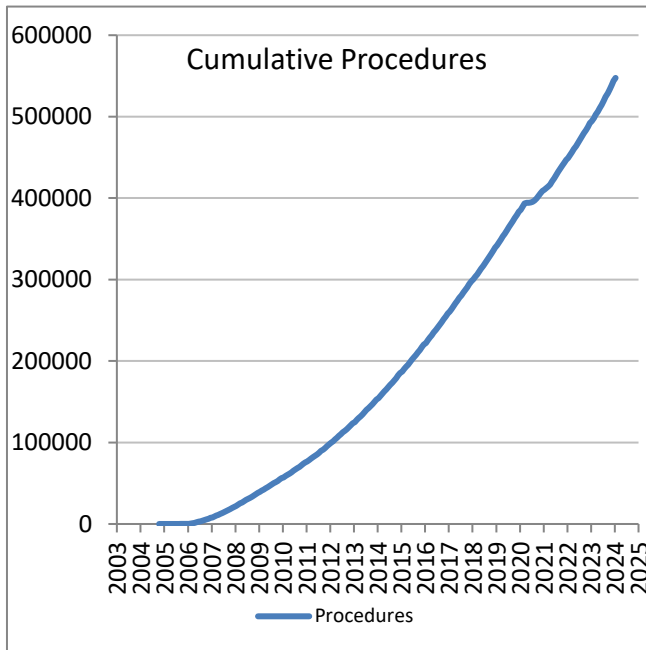
Date of first recorded usage in the NJR: **06 September 2005**

Date of last recorded usage in this dataset: **13 January 2024**

Maximum implantation time: 18.3 years

Mean implantation time: 6.0 years

Totals Recorded in NJR	Cumulative Total
Procedures	547,693
Patients	483,967
Centres	452
Consultants	3,537
Implanting Surgeons	6,182



Current Outcome	Year of implantation													Total	%
	Pre-2013	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024		
Death	55964	8824	8529	7741	6941	5701	4576	3474	1348	1161	569	341	5	105174	19.2%
Revised	4463	687	705	751	707	672	601	561	293	374	323	255	0	10392	1.9%
Unrevised	64018	19723	23446	26525	30618	33254	36283	39958	23549	36972	44132	51932	1717	432127	78.9%
Total	1E+05	29234	32680	35017	38266	39627	41460	43993	25190	38507	45024	52528	1722	547693	100%

Patient / Procedure Details

Patient Details

	Hips using Palacos Antibiotic Cement	All other cement brands in NJR	All NJR hip replacement
Total Procedures	547,693	425,084	1,600,803
Total Patients	483,967	377,907	1,328,627
Demographics			
Mean age	71.8	70.6	68.8
< 50	3.2%	4.9%	6.1%
50 – 59	9.5%	11.3%	14.5%
60 – 69	25.1%	25.6%	29.1%
70 – 79	40.6%	38.4%	34.6%
≥ 80	21.5%	19.7%	15.7%
Median BMI	28	28	28
% BMI information available	71.7%	57.7%	65.7%
Underweight (BMI < 18.5)	1.0%	1.1%	0.9%
Normal (18.5 ≤ BMI < 25)	21.9%	22.7%	20.9%
Overweight (25 ≤ BMI < 30)	39.2%	39.7%	39.2%
Obese I (30 ≤ BMI < 35)	25.3%	24.5%	25.7%
Obese II (35 ≤ BMI < 40)	9.4%	9.0%	9.9%
Obese III (BMI ≥ 40)	3.1%	2.9%	3.3%
% Male	35.7%	38.1%	40.2%
ASA Grades			
P1 - Fit and healthy	9.6%	14.9%	14.2%
P2 - Mild disease not incapacitating	68.0%	64.9%	67.6%
P3 - Incapacitating systemic disease	21.4%	19.3%	17.4%
P4 / P5	0.9%	0.9%	0.7%
Indications			
Osteoarthritis	88.82%	89.38%	90.65%
Rheumatoid Arthritis	1.39%	1.39%	1.29%
Avascular Necrosis	2.63%	2.60%	2.61%
Fractured Neck of Femur	5.22%	4.61%	3.72%
CDH/DDH	1.11%	1.29%	1.60%
Other	3.37%	3.27%	2.74%

Total of indications may exceed total number of implants, since more than one indication can be listed per case.

Revision and Survivorship

Reasons for Revision - all bearing types

Reasons for revision of primary procedures in which the implant was used.

Reason for Revision	Revised [†]	Expected Revisions [*]	p value
Unexplained Pain	597	702.23	<0.001
Dislocation / Subluxation	2563	2582.66	0.582
Adverse Soft Tissue Reaction	406	524.11	<0.001
Infection	2357	2429.92	0.033
Aseptic Loosening - Stem	799	916.47	<0.001
Aseptic Loosening - Socket	1589	1615.43	0.417
Periprosthetic Fracture Stem	1941	2024.71	0.009
Periprosthetic Fracture Socket	192	202.23	0.319
Malalignment Stem	224	246.43	0.054
Malalignment Socket	466	447.74	0.253
Wear Of Acetabular Component	389	368.87	0.202
Lysis Stem	249	261.16	0.373
Lysis Socket	374	361.36	0.427
Implant Fracture Stem	194	195.20	0.927
Implant Fracture Socket	41	43.73	0.625
Implant Fracture Head	44	46.24	0.705
Dissociation of Liner	120	111.84	0.292
Other / reason not recorded	440	466.47	0.115
Total Revised	10392	10863.66	<0.001

[†] multiple reasons may be listed for one revision procedure

^{*} Based on All NJR Hips with Cement, adjusted for agegroup, gender, indications, and implantation year

Significantly better, p < 0.001

Significantly better, p < 0.05

Significantly worse p < 0.05

Significantly worse p < 0.001



Components Revised	Number of procedures	Hips using Palacos Antibiotic Cement	All other cement brands in NJR
Femoral only	2487	24%	18%
Acetabular only	2165	21%	18%
Both femoral and acetabular	4386	42%	58%
Neither femoral nor acetabular revision recorded [*]	1354	13%	6%

^{*} includes isolated head and/or liner exchange

Revision and Survivorship

Reasons for Revision - excluding Metal on Metal

Reasons for revision of non-MoM primary procedures in which the implant was used.

Reason for Revision	Revised [†]	Expected Revisions [*]	p value
Unexplained Pain	460	469.68	0.566
Dislocation / Subluxation	2544	2590.73	0.183
Adverse Soft Tissue Reaction	145	133.05	0.183
Infection	2323	2423.63	0.002
Aseptic Loosening - Stem	728	841.43	<0.001
Aseptic Loosening - Socket	1538	1571.61	0.275
Periprosthetic Fracture Stem	1870	1925.61	0.064
Periprosthetic Fracture Socket	190	196.11	0.527
Malalignment Stem	216	233.06	0.106
Malalignment Socket	437	418.69	0.212
Wear Of Acetabular Component	381	369.71	0.473
Lysis Stem	213	217.36	0.735
Lysis Socket	333	319.97	0.36
Implant Fracture Stem	184	192.62	0.409
Implant Fracture Socket	41	41.99	0.917
Implant Fracture Head	39	42.32	0.511
Dissociation of Liner	118	107.71	0.162
Other / reason not recorded	379	378.88	1
Total Revised	9755	10061.39	<0.001

* Based on All NJR Hips with Cement (excluding metal on metal), adjusted for agegroup, gender, indications, and implantation year

† multiple reasons may be listed for one revision procedure

- Significantly better, p < 0.001
- Significantly better, p < 0.05
- Significantly worse p < 0.05
- Significantly worse p < 0.001



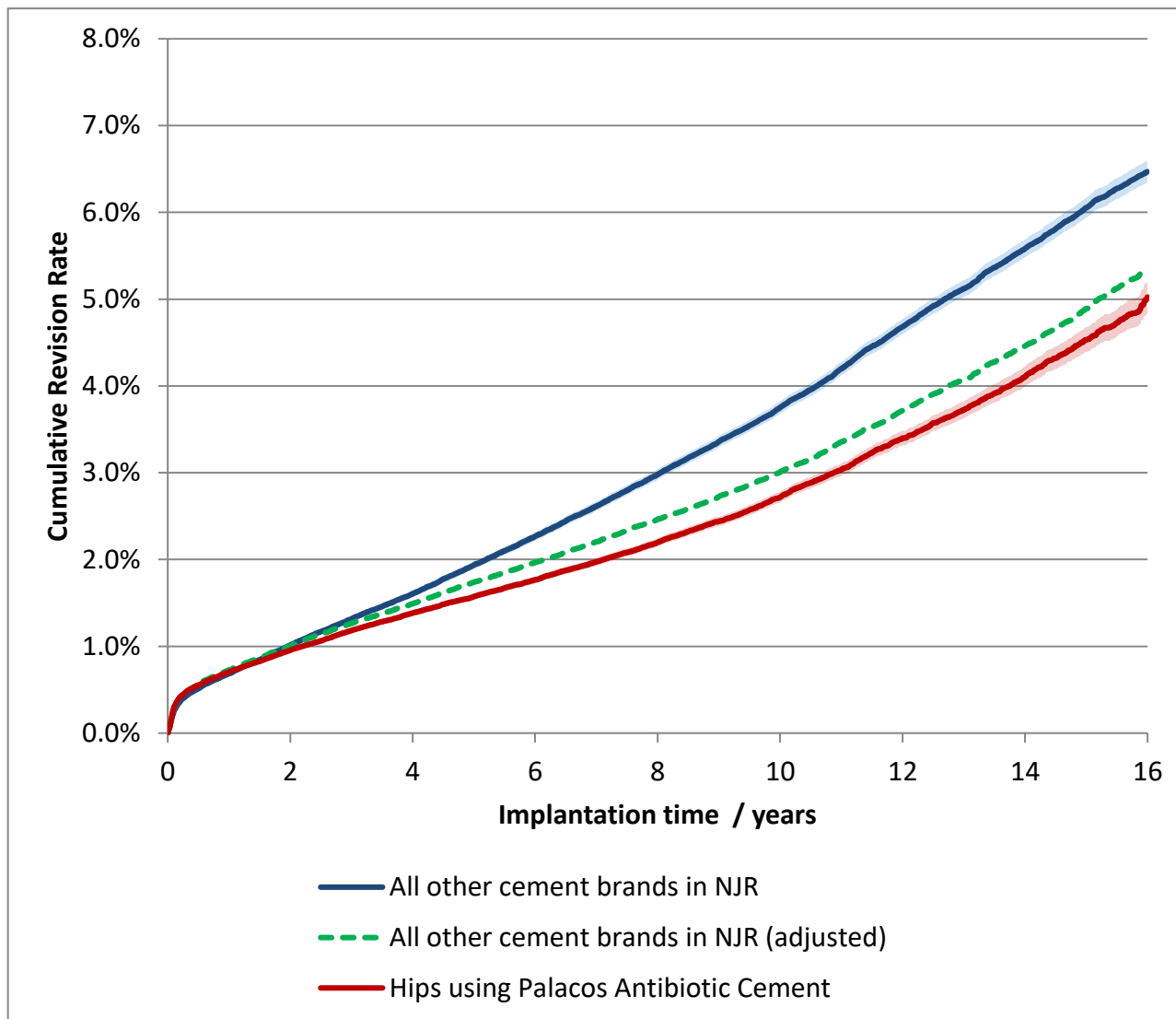
Components Revised	Number of procedures	Hips using Palacos Antibiotic Cement	All other cement brands in NJR
Femoral only	2434	25%	21%
Acetabular only	2104	22%	24%
Both femoral and acetabular	3873	40%	47%
Neither femoral nor acetabular revision recorded *	1344	14%	8%

* includes isolated head and/or liner exchange

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision. All Bearing types



Cox Proportional Hazards model for revision risk ratio of Hips using Palacos Antibiotic Cement / All other cement brands in NJR, with endpoint as any revision.

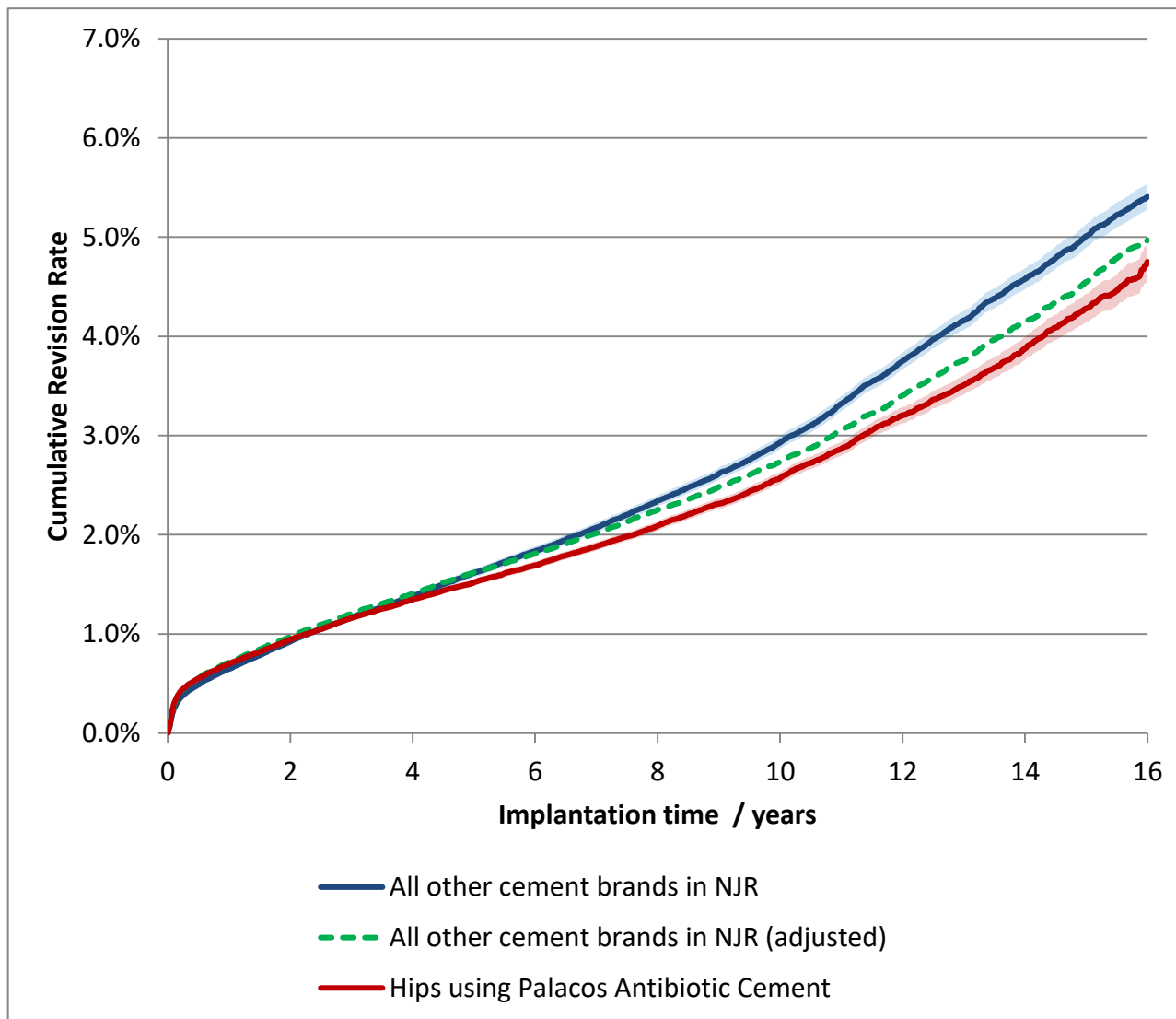
Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	0.77 ‡ (0.75 - 0.79)	<0.001 ‡
All bearings. Adjusted for age, gender, year cohort and indications.	0.91 (0.88 - 0.93)	<0.001

‡ Hazard ratio varies with time

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision. Excluding Metal-on-Metal



Cox Proportional Hazards model for revision risk ratio of Hips using Palacos Antibiotic Cement / All other cement brands in NJR, with endpoint as any revision.

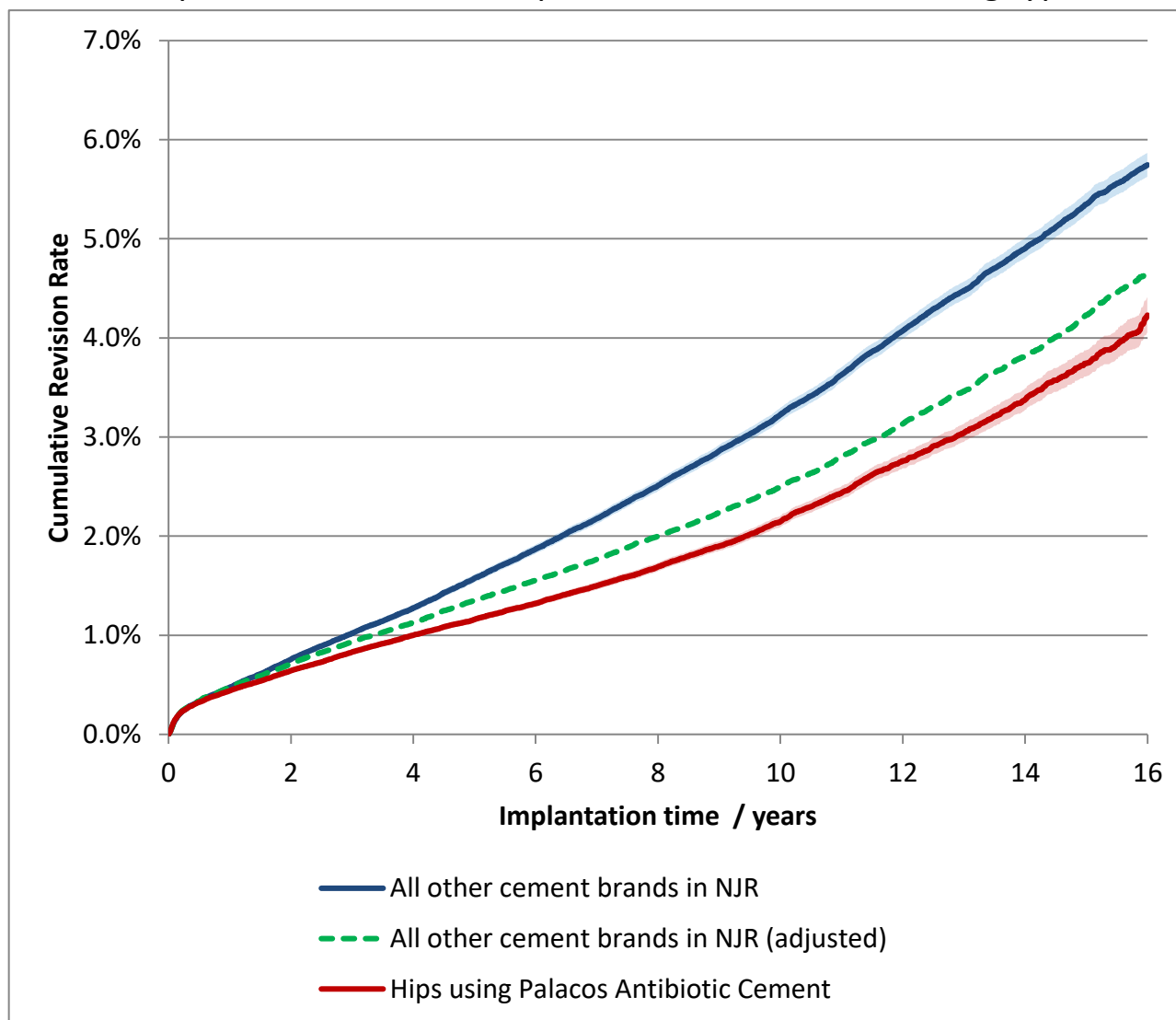
Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted.	0.90 ‡ (0.87 - 0.92)	<0.001 ‡
Excluding MoM. Adjusted for age, gender, year cohort and indications.	0.93 (0.90 - 0.96)	<0.001

‡ Hazard ratio varies with time

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Cemented Component Revision. All Bearing types



Cox Proportional Hazards model for revision risk ratio of Hips using Palacos Antibiotic Cement / All other cement brands in NJR, with endpoint as any revision.

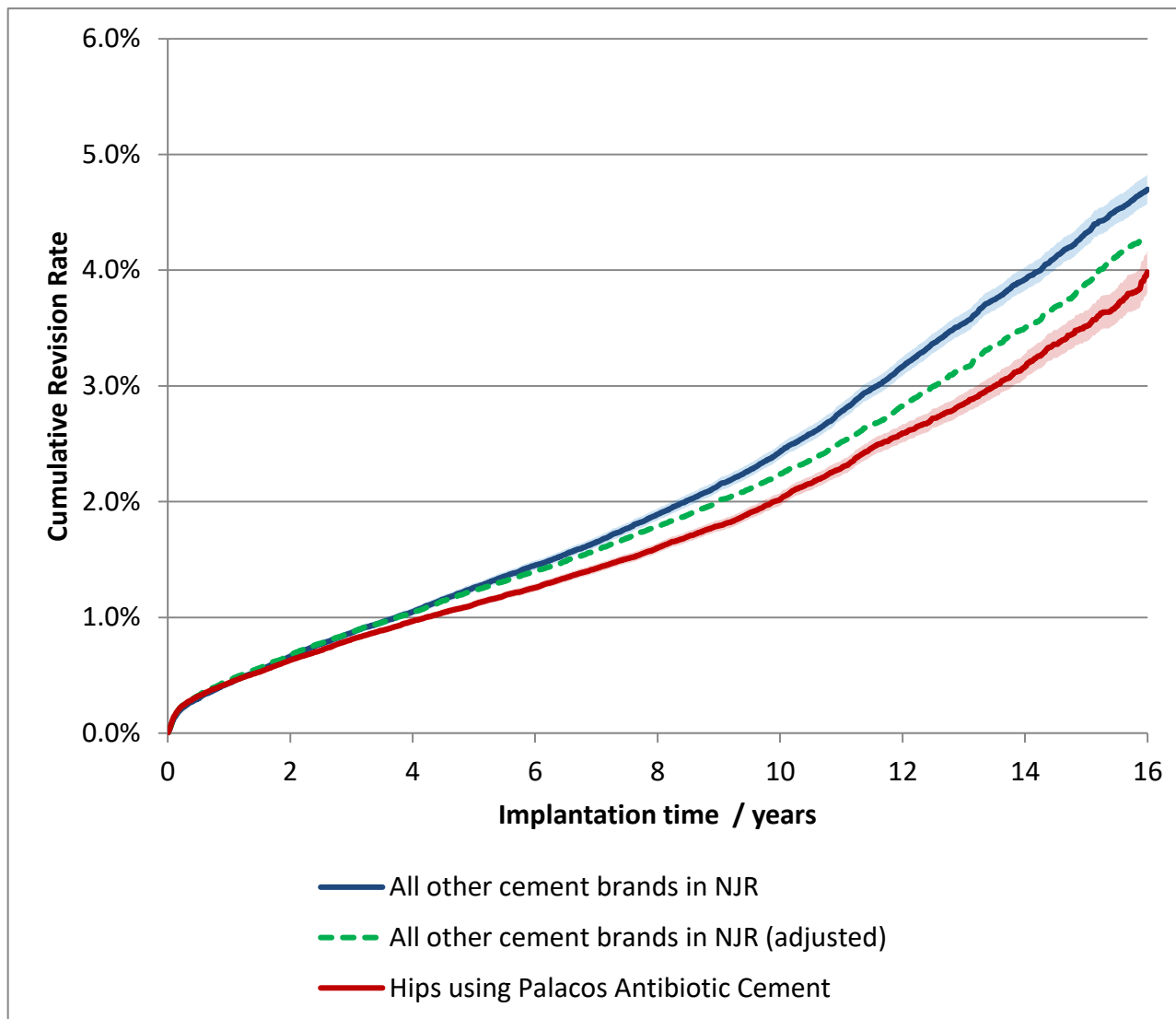
Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	0.70 ‡ (0.68 - 0.73)	<0.001 ‡
All bearings. Adjusted for age, gender, year cohort and indications.	0.87 (0.84 - 0.89)	<0.001

‡ Hazard ratio varies with time

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Cemented Component Revision. Excluding Metal-on-Metal



Cox Proportional Hazards model for revision risk ratio of Hips using Palacos Antibiotic Cement / All other cement brands in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM. Unadjusted.	0.85 ‡ (0.82 - 0.88)	<0.001 ‡
Excluding MoM. Adjusted for age, gender, year cohort and indications.	0.90 (0.87 - 0.93)	<0.001

‡ Hazard ratio varies with time

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All revisions

Period /years	All Bearing types				Excluding Metal on Metal Bearings			
	At Risk	Hips using Palacos Antibiotic Cement	All other cement brands in NJR	All THR	At Risk	Hips using Palacos Antibiotic Cement	All other cement brands in NJR	All THR
0	547,693	-	-	-	542,466	-	-	-
1	483,157	0.7% (0.7% - 0.7%)	0.7% (0.7% - 0.7%)	0.8% (0.8% - 0.8%)	478,135	0.7% (0.7% - 0.7%)	0.6% (0.6% - 0.7%)	0.8% (0.7% - 0.8%)
2	429,611	1.0% (0.9% - 1.0%)	1.0% (1.0% - 1.0%)	1.1% (1.1% - 1.1%)	424,772	0.9% (0.9% - 1.0%)	0.9% (0.9% - 1.0%)	1.0% (1.0% - 1.1%)
3	382,276	1.2% (1.2% - 1.2%)	1.3% (1.3% - 1.4%)	1.4% (1.4% - 1.4%)	377,587	1.2% (1.1% - 1.2%)	1.2% (1.1% - 1.2%)	1.3% (1.3% - 1.3%)
4	348,297	1.4% (1.4% - 1.4%)	1.6% (1.6% - 1.6%)	1.7% (1.6% - 1.7%)	343,763	1.3% (1.3% - 1.4%)	1.4% (1.3% - 1.4%)	1.5% (1.5% - 1.5%)
5	297,692	1.6% (1.5% - 1.6%)	1.9% (1.9% - 2.0%)	2.0% (1.9% - 2.0%)	293,328	1.5% (1.5% - 1.6%)	1.6% (1.6% - 1.7%)	1.7% (1.7% - 1.7%)
6	250,762	1.8% (1.7% - 1.8%)	2.3% (2.2% - 2.3%)	2.3% (2.3% - 2.3%)	246,566	1.7% (1.7% - 1.7%)	1.8% (1.8% - 1.9%)	1.9% (1.9% - 1.9%)
7	207,682	2.0% (1.9% - 2.0%)	2.6% (2.6% - 2.7%)	2.6% (2.6% - 2.6%)	203,632	1.9% (1.8% - 1.9%)	2.1% (2.0% - 2.1%)	2.1% (2.1% - 2.1%)
8	168,093	2.2% (2.1% - 2.2%)	3.0% (2.9% - 3.0%)	3.0% (2.9% - 3.0%)	164,213	2.1% (2.0% - 2.1%)	2.3% (2.3% - 2.4%)	2.4% (2.3% - 2.4%)
9	133,383	2.4% (2.4% - 2.5%)	3.4% (3.3% - 3.4%)	3.3% (3.3% - 3.4%)	129,678	2.3% (2.3% - 2.4%)	2.6% (2.6% - 2.7%)	2.6% (2.6% - 2.6%)
10	103,094	2.7% (2.7% - 2.8%)	3.8% (3.7% - 3.8%)	3.7% (3.6% - 3.7%)	99,571	2.6% (2.5% - 2.6%)	2.9% (2.9% - 3.0%)	2.9% (2.8% - 2.9%)
11	77,652	3.0% (3.0% - 3.1%)	4.2% (4.1% - 4.3%)	4.1% (4.0% - 4.1%)	74,299	2.9% (2.8% - 2.9%)	3.3% (3.2% - 3.4%)	3.2% (3.2% - 3.2%)
12	57,184	3.4% (3.3% - 3.5%)	4.7% (4.6% - 4.8%)	4.5% (4.5% - 4.6%)	54,039	3.2% (3.1% - 3.3%)	3.7% (3.7% - 3.8%)	3.6% (3.5% - 3.6%)
13	40,643	3.7% (3.6% - 3.8%)	5.1% (5.0% - 5.2%)	5.0% (4.9% - 5.1%)	37,867	3.5% (3.4% - 3.6%)	4.2% (4.1% - 4.3%)	3.9% (3.9% - 4.0%)
14	27,872	4.1% (4.0% - 4.2%)	5.6% (5.5% - 5.7%)	5.5% (5.4% - 5.5%)	25,484	3.9% (3.8% - 4.0%)	4.6% (4.5% - 4.7%)	4.3% (4.3% - 4.4%)
15	17,577	4.5% (4.4% - 4.7%)	6.0% (5.9% - 6.2%)	6.0% (5.9% - 6.0%)	15,792	4.3% (4.1% - 4.4%)	5.0% (4.9% - 5.1%)	4.8% (4.7% - 4.8%)

Cumulative revision rate with 95% confidence intervals

Rate is only reported for times where more than 40 remain at risk

Cumulative Revision Rate

Endpoint: Cemented Component Revision

Period /years	All Bearing types				Excluding Metal on Metal Bearings			
	At Risk	Hips using Palacos Antibiotic Cement	All other cement brands in NJR	All THR	At Risk	Hips using Palacos Antibiotic Cement	All other cement brands in NJR	All THR
0	547,693	-	-	-	542,466	-	-	-
1	483,157	0.4% (0.4% - 0.5%)	0.5% (0.5% - 0.5%)	(-)	478,135	0.4% (0.4% - 0.5%)	0.4% (0.4% - 0.5%)	(-)
2	429,611	0.6% (0.6% - 0.7%)	0.8% (0.7% - 0.8%)	(-)	424,772	0.6% (0.6% - 0.7%)	0.7% (0.6% - 0.7%)	(-)
3	382,276	0.8% (0.8% - 0.9%)	1.0% (1.0% - 1.1%)	(-)	377,587	0.8% (0.8% - 0.8%)	0.9% (0.8% - 0.9%)	(-)
4	348,297	1.0% (1.0% - 1.0%)	1.3% (1.2% - 1.3%)	(-)	343,763	1.0% (0.9% - 1.0%)	1.0% (1.0% - 1.1%)	(-)
5	297,692	1.2% (1.1% - 1.2%)	1.6% (1.5% - 1.6%)	(-)	293,328	1.1% (1.1% - 1.1%)	1.3% (1.2% - 1.3%)	(-)
6	250,762	1.3% (1.3% - 1.4%)	1.9% (1.8% - 1.9%)	(-)	246,566	1.3% (1.2% - 1.3%)	1.5% (1.4% - 1.5%)	(-)
7	207,682	1.5% (1.5% - 1.5%)	2.2% (2.1% - 2.2%)	(-)	203,632	1.4% (1.4% - 1.5%)	1.7% (1.6% - 1.7%)	(-)
8	168,093	1.7% (1.6% - 1.7%)	2.5% (2.5% - 2.6%)	(-)	164,213	1.6% (1.6% - 1.6%)	1.9% (1.8% - 1.9%)	(-)
9	133,383	1.9% (1.9% - 1.9%)	2.9% (2.8% - 2.9%)	(-)	129,678	1.8% (1.7% - 1.8%)	2.1% (2.1% - 2.2%)	(-)
10	103,094	2.1% (2.1% - 2.2%)	3.2% (3.2% - 3.3%)	(-)	99,571	2.0% (2.0% - 2.1%)	2.4% (2.4% - 2.5%)	(-)
11	77,652	2.4% (2.4% - 2.5%)	3.6% (3.6% - 3.7%)	(-)	74,299	2.3% (2.2% - 2.4%)	2.8% (2.7% - 2.9%)	(-)
12	57,184	2.8% (2.7% - 2.8%)	4.1% (4.0% - 4.2%)	(-)	54,039	2.6% (2.5% - 2.7%)	3.2% (3.1% - 3.2%)	(-)
13	40,643	3.0% (3.0% - 3.1%)	4.5% (4.4% - 4.6%)	(-)	37,867	2.8% (2.8% - 2.9%)	3.5% (3.5% - 3.6%)	(-)
14	27,872	3.4% (3.3% - 3.5%)	4.9% (4.8% - 5.0%)	(-)	25,484	3.2% (3.1% - 3.3%)	3.9% (3.8% - 4.0%)	(-)
15	17,577	3.7% (3.6% - 3.9%)	5.3% (5.2% - 5.5%)	(-)	15,792	3.5% (3.4% - 3.6%)	4.3% (4.2% - 4.4%)	(-)

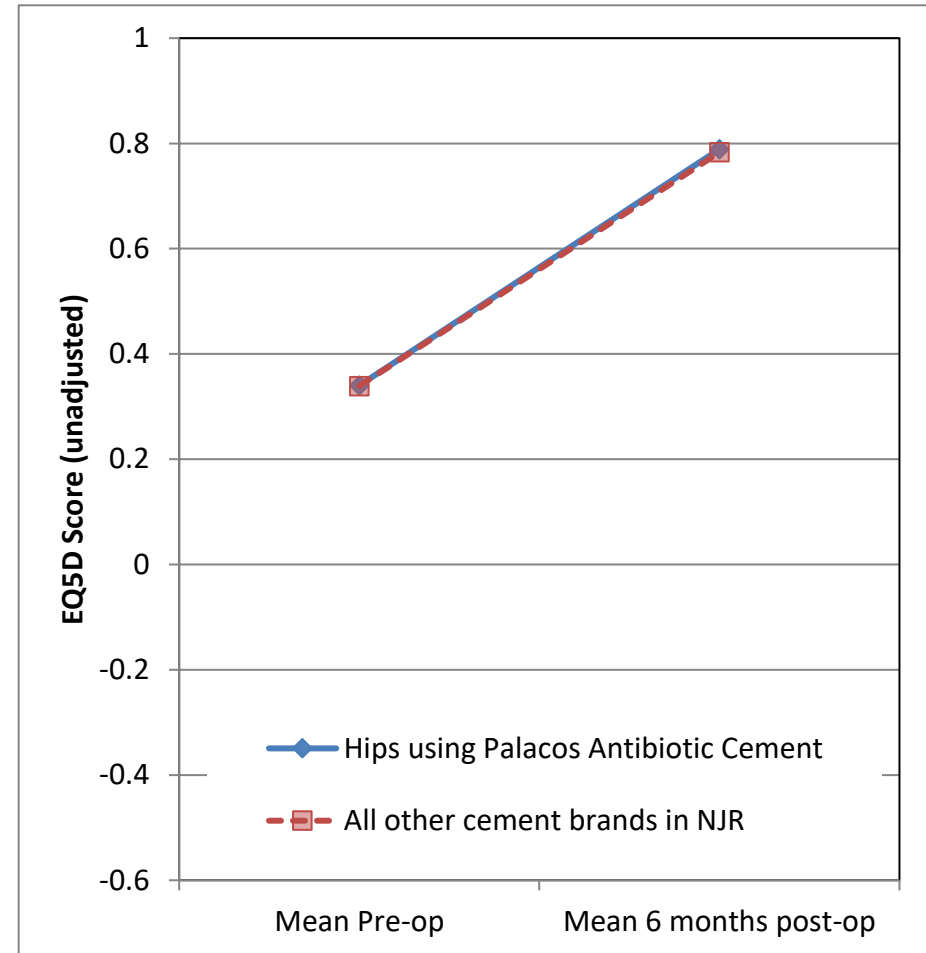
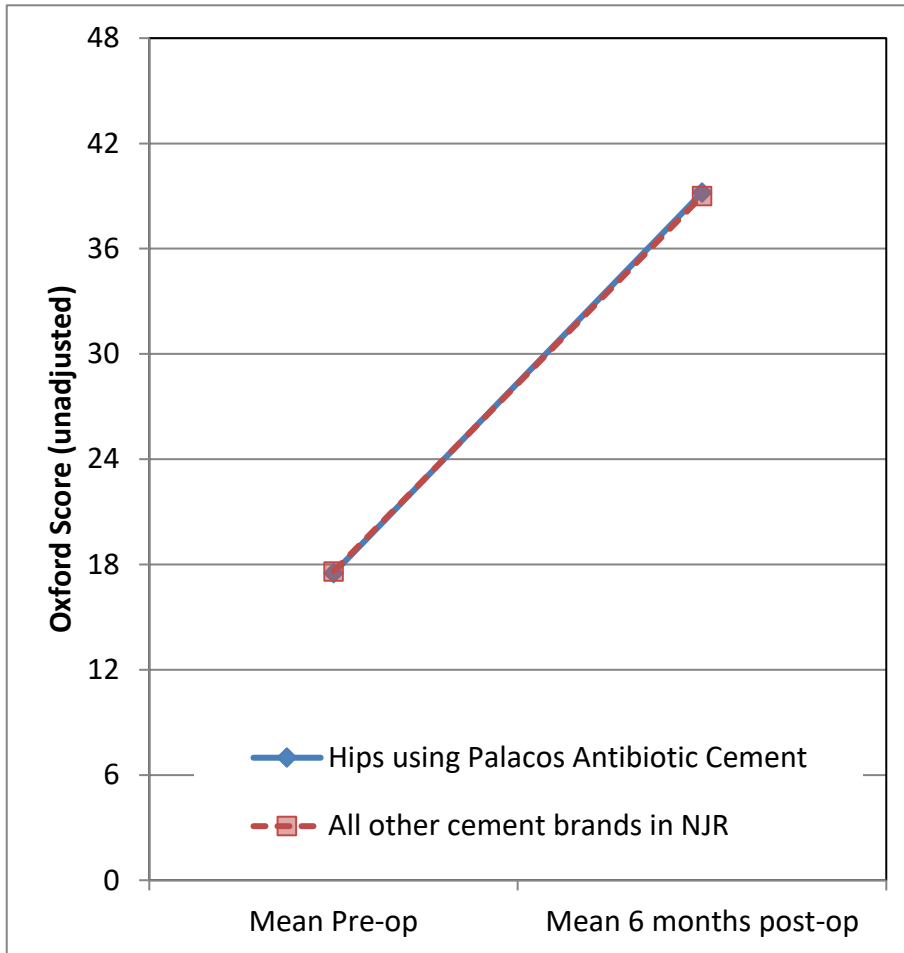
Cumulative revision rate with 95% confidence intervals

Rate is only reported for times where more than 40 remain at risk

Patient Reported Outcomes

Comprising PROMs data up to and including: 31/12/2020

PROMs Analysis



Patient Reported Outcomes

PROMs Analysis

Comprising PROMs data up to and including: 31/12/2020

Oxford Hip Score (0 - 48)	Hips using Palacos Antibiotic Cement	All other cement brands in NJR	All THR in NJR
Paired Records	125,335	83,086	350,453
PreOp score	17.5 (17.5 - 17.6)	17.6 (17.5 - 17.6)	17.9 (17.9 - 18.0)
6 month score	39.2 (39.2 - 39.3)	39.0 (38.9 - 39.0)	39.6 (39.5 - 39.6)
6 month score (adjusted)	39.5 (39.5 - 39.5)	39.4 (39.3 - 39.4)	39.6 (39.5 - 39.6)
Health gain	21.7 (21.6 - 21.7)	21.4 (21.3 - 21.4)	21.6 (21.6 - 21.7)
Health gain (adjusted)	21.6 (21.5 - 21.6)	21.4 (21.4 - 21.5)	21.6 (21.6 - 21.7)
p value (adjusted health gain)	0.001		
Score Improved	97.4%	97.2%	97.3%

EQ-5D Index (-0.59 - 1.00)	Hips using Palacos Antibiotic Cement	All other cement brands in NJR	All THR in NJR
Paired Records	115,107	76,354	323,116
PreOp score	0.340 (0.339 - 0.342)	0.339 (0.337 - 0.342)	0.353 (0.352 - 0.354)
6 month score	0.789 (0.788 - 0.790)	0.783 (0.781 - 0.784)	0.795 (0.794 - 0.796)
6 month score (adjusted)	0.793 (0.792 - 0.795)	0.791 (0.789 - 0.792)	0.795 (0.794 - 0.796)
Health gain	0.449 (0.447 - 0.451)	0.443 (0.441 - 0.446)	0.442 (0.441 - 0.443)
Health gain (adjusted)	0.440 (0.439 - 0.441)	0.437 (0.436 - 0.439)	0.442 (0.441 - 0.443)
p value (adjusted health gain)	0.16		
Score Improved	89.8%	89.5%	89.7%

EQ-VAS (0 - 100)	Hips using Palacos Antibiotic Cement	All other cement brands in NJR	All THR in NJR
Paired Records	110,274	73,502	310,929
PreOp score	64.4 (64.3 - 64.5)	64.4 (64.2 - 64.5)	64.7 (64.7 - 64.8)
6 month score	76.6 (76.5 - 76.7)	76.0 (75.9 - 76.2)	77.0 (77.0 - 77.1)
6 month score (adjusted)	77.0 (76.9 - 77.1)	76.7 (76.6 - 76.9)	77.0 (77.0 - 77.1)
Health gain	12.2 (12.1 - 12.3)	11.7 (11.5 - 11.8)	12.3 (12.2 - 12.4)
Health gain (adjusted)	12.3 (12.2 - 12.4)	12.0 (11.9 - 12.1)	12.3 (12.3 - 12.4)
p value (adjusted health gain)	0.001		
Score Improved	66.2%	65.2%	66.6%

Adjusted scores correspond to the NHS Digital version 3 casemix-adjustment model. This includes patient variables from PROMs, HES, and IMD data.

Figures in parentheses represent the 95% confidence interval for the mean

Summary Report for:

Hips using Palacos Antibiotic Cement

Responses are not case mix adjusted

Patient Reported Outcomes



Patient Reported Outcomes

Success

Response	Hips using Palacos Antibiotic Cement	All other cement brands in NJR
Much better	110401	73008
A little better	11050	7504
About the same	2985	2068
A little worse	1720	1131
Much worse	1142	732

Answer to 6-months general health question:

"Overall, how are your problems now, compared to before your operation?"

Satisfaction

Response	Hips using Palacos Antibiotic Cement	All other cement brands in NJR
Excellent	51610	34350
Very Good	44544	29301
Good	21806	14449
Fair	7211	4870
Poor	1957	1328

Answer to 6-months general health question:

"How would you describe the results of your operation?"

Disclaimer

Disclaimer

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Appendix A: Component List

Catalogue Number	Description	Number Implanted
Cement		
66017569	PALACOS R +G 2x40 g	480548
66017771	PALACOS R +G 1x40 g	3518
66017772	PALACOS R +G 1x60 g	7693
66017773	PALACOS R +G 2x20 g	5205
66017776	PALACOS R +G 2x10 g	7
66017787	PALACOS LV +G 1x40 g	4891
66031993	PALACOS MV+G 1x40g	231
66031995	PALACOS MV+G 2x40 g	2667
66031996	PALACOS MV+G 1x20g	2
66031998	PALACOS MV+G 2x20 g	15
66032000	PALACOS MV+G 1x60 g	1
66037894	PALACOS LV+G 1x20g	1
66044273	PALACOS R+G Pro 55 cement	177
66044274	PALACOS R+G Pro 75 cement	713
Multiple Found	Multiple Found	42024